# UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

CAMBRIDGE RETIREMENT SYSTEM, on behalf of Itself and all Others Similarly	) CASE NO. 1:13-cv-1165-CAB
Situated,	) JUDGE CHRISTOPHER A. BOYKO
Plaintiff,	
v.	) SEPARATE ANSWER OF DEFENDANT ) GERALD B. BLOUCH TO AMENDED
INVACARE CORPORATION, et al.,	) COMPLAINT
Defendants.	)

For his Answer to Plaintiff's Amended Complaint, Defendant Gerald B. Blouch ("Defendant" or "Blouch") states as follows:

## I. INTRODUCTION

Lead Plaintiff's Introduction appears to express its characterization of this action and conclusory statements, not allegations of fact, and thus no response is deemed required. To the extent that the allegations can be construed to constitute allegations of material facts to which a response is required, the allegations are denied.

#### II. NATURE AND SUMMARY OF THE ACTION

1. In response to Paragraph 1 of the Amended Complaint, Blouch admits that Invacare is a manufacturer and distributor of home and long-term care medical products, admits that he was the Company's President and CEO, admits that Mixon was its Chairman, founder and was its former CEO, admits that Invacare sells power and manual wheelchairs and homecare bed systems, and denies the remaining allegations.

- 2. In response to Paragraph 2 of the Amended Complaint, Blouch admits that Invacare entered into a consent decree with the FDA. Blouch states that the consent decree speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 2 is inconsistent with the consent decree, it is denied. Blouch denies the remaining allegation.
  - 3. Blouch admits the allegations in Paragraph 3 of the Amended Complaint.
- 4. In response to Paragraph 4 of the Amended Complaint, Blouch admits that Invacare is subject to periodic inspections by the FDA to ensure compliance with the Federal Food, Drug, and Cosmetic Act ("FDCA") and other applicable laws and regulations and that the issuance of a Form 483 is a serious matter. Blouch denies the remaining allegations in Paragraph 4 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 5. In response to Paragraph 5 of the Amended Complaint, Blouch admits that the issuance of a Warning Letter is a serious matter and denies the remaining allegations for want of knowledge or information sufficient to form a belief as to their truth.
- 6. In response to Paragraph 6 of the Amended Complaint, Blouch admits that Invacare was subject to FDA inspections and received observations and certain Form 483s and Warning Letters and admits that certain violations have been identified by the FDA. Blouch further states that the referenced Form 483s and Warning Letters speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 6 is inconsistent with the referenced Form 483s and Warning Letters, it is denied.
  - 7. Blouch denies the allegations in Paragraph 7 of the Amended Complaint.

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- 8. In response to Paragraph 8 of the Amended Complaint, Blouch denies all allegations relating to statements made by former Invacare employees for want of knowledge or information sufficient to form a belief as to their truth and denies the remaining allegations.
- 9. In response to Paragraph 9 of the Amended Complaint, Blouch denies all allegations relating to statements made by former Invacare employees for want of knowledge or information sufficient to form a belief as to their truth and denies the remaining allegations.
- 10. In response to Paragraph 10 of the Amended Complaint, Blouch admits that Invacare received two Form 483s on December 17, 2010 and denies the remaining allegations.
- 11. In response to Paragraph 9 of the Amended Complaint, Blouch denies all allegations relating to statements made by former Invacare employees for want of knowledge or information sufficient to form a belief as to their truth and denies the remaining allegations.
- 12. In response to Paragraph 12 of the Amended Complaint, Blouch admits that Invacare issued a press release on December 8, 2011 (the "December 8, 2011 Press Release"), admits that the FDA filed a Complaint For Permanent Injunction against the Company, admits that Invacare and the U.S. Government entered into a Consent Decree (the "Consent Decree"), and admits that at least 40% of the hourly workforce at the Taylor Street Facility was permanently laid off. Blouch states that the December 8, 2011 Press Release, the Complaint for Permanent Injunction, and Consent Decree speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 12 is inconsistent with the December 8, 2011 Press Release, the Complaint for Permanent Injunction, and Consent Decree, it is denied. Blouch denies the remaining allegations.
- 13. In response to Paragraph 13 of the Amended Complaint, Blouch admits that the FDA disclosed the December 2010 Warning Letter on January 4, 2011, admits that the price of {02648654.DOCX;5}

Invacare stock declined from \$30.67 per share on January 3, 2011, to close at \$29.29 per share on January 4, 2011, admits that Invacare disclosed the FDA's intent to seek a consent decree on December 8, 2011, and admits that the price of Invacare stock declined from \$20.58 per share on December 7, 2011, to close at \$14.70 per share on December 8, 2011. Blouch denies the remaining allegations.

- 14. In response to Paragraph 14 of the Amended Complaint, Blouch denies the allegations regarding the referenced chart for want of knowledge or information sufficient to form a belief as to their truth, and otherwise denies the remaining allegations.
- 15. In response to Paragraph 15 of the Amended Complaint, Blouch admits that Invacare is a home medical equipment product supplier, admits that it has employed as many as approximately 6,100 individuals at one time, admits that the Company's corporate headquarters is located at One Invacare Way, Elyria, Ohio, admits that Invacare also has a manufacturing facility in Elyria, and admits that Mixon suffered a stroke in 2010. Further, Blouch denies unattributed quotes contained in Paragraph 15 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth, and denies the remaining allegations.
- 16. In response to Paragraph 16 of the Amended Complaint, Blouch states that the FDA's Complaint for Permanent Injunction speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 16 is inconsistent with the Complaint for Permanent Injunction, it is denied. Further, Blouch denies that the "Consent Decree came as no surprise."
  - 17. Blouch denies the allegations in Paragraph 17 of the Amended Complaint.

# III. JURISDICTION AND VENUE

- 18. The allegations in Paragraph 18 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.
- 19. The allegations in Paragraph 19 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.
- 20. The allegations in Paragraph 20 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.
- 21. The allegations in Paragraph 21 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.

## IV. PARTIES

## A. Lead Plaintiff

22. In response to Paragraph 22 of the Amended Complaint, Blouch admits that Lead Plaintiff, the Government of Guam Retirement Fund, was appointed by the Court as Lead Plaintiff by Order dated October 1, 2013 and denies the remaining allegations for want of knowledge or information sufficient to form a belief as to their truth.

## B. <u>Defendants</u>

23. In response to Paragraph 23 of the Amended Complaint, Blouch states that Invacare sells products to the Veterans Administration and denies that Invacare serves as a contractor to other government agencies. Blouch admits the remaining allegations.

- 24. In response to Paragraph 24 of the Amended Complaint, Blouch denies that homecare bed and manual and powered wheelchairs account for approximately half of Invacare's sales and revenue, and admits the remaining allegations.
- 25. In response to Paragraph 25 of the Amended Complaint, Blouch admits that he was Invacare's President and CEO, admits that he had certain oversight responsibilities, admits that he previously served as interim CEO of Invacare from April 30, 2010, through December 31, 2010, admits that he joined the Company in 1990 as its first Chief Financial Officer ("CFO"), and became the Company's Chief Operating Officer in 1994, admits that he has also served as President and a Director of Invacare, and denies the remaining allegations.
  - 26. Blouch admits the allegations in Paragraph 26 of the Amended Complaint.
- In response to Paragraph 27 of the Amended Complaint, Blouch admits that Invacare issued press releases on April 30, 2010 and July 17, 2010 (respectively, the "April 30, 2010 Press Release" and "July 17, 2010 Press Release"). Blouch states that the April 30, 2010 Press Release and July 17, 2010 Press Release speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 27 is inconsistent with the April 30, 2010 Press Release and July 17, 2010 Press Release, it is denied.
  - 28. Blouch admits the allegations in Paragraph 28 of the Amended Complaint.
- 29. In response to Paragraph 29 of the Amended Complaint, Blouch admits that Individual Defendants signed the Company's SEC filings. Blouch states that the remaining allegations in Paragraph 29 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.

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# V. CONFIDENTIAL WITNESSES

- 30. Blouch denies the allegations in Paragraph 30 of the Amended Complaint.
- 31. In response to Paragraph 31 of the Amended Complaint, Blouch admits that Jeffrey Craigo was employed by Invacare, admits that, as part of his duties, Craigo oversaw Regulatory Affairs, and admits that Craigo reported to Blouch. Blouch denies the remaining allegations for want of knowledge or information sufficient to form a belief as to their truth.
- 32. In response to Paragraph 32 of the Amended Complaint, Blouch admits that 143 employees were laid off by the Company on December 27, 2012. Blouch denies the remaining allegations for want of knowledge or information sufficient to form a belief as to their truth.
- 33. Blouch denies the allegations in Paragraph 33 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 34. In response to Paragraph 34 of the Amended Complaint, Blouch admits that he, Slangen, Uelmen, Remmers, Stumpp, LaPlaca, Mewes, Sutherland, and Gudbranson have held positions on the Company's Executive Committee. Blouch denies the remaining allegations for want of knowledge or information sufficient to form a belief as to their truth.
- 35. Blouch denies the allegations in Paragraph 35 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 36. In response to Paragraph 36 of the Amended Complaint, Blouch admits that Lynda Bell and Rob Boeye were previously employed at the Company as Director of HCS and Vice President of Sales, respectively. Blouch denies the remaining allegations for want of knowledge or information sufficient to form a belief as to their truth.
- 37. Blouch denies the allegations in Paragraph 37 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.

- 38. Blouch denies the allegations in Paragraph 38 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 39. Blouch denies the allegations in Paragraph 39 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.

## VI. DEFENDANTS' VIOLATIONS OF THE FEDERAL SECURITIES LAWS

### A. Company Background

- 40. Blouch admits the allegations in Paragraph 40 of the Amended Complaint.
- 41. In response to Paragraph 41 of the Amended Complaint, Blouch admits that the Company made acquisitions between 1995 and 2008, admits that the Company's product lines include oxygen concentrators, beds, and patient furniture, admits that net sales grew from \$19.5 million in 1979 to approximately \$1.8 billion by 2012, admits that the Company has employed as many as approximately 6,100 individuals at one time, admits that it was a NYSE corporation listed on the "Fortune 1000," and denies the remaining allegations.
  - 42. Blouch denies the allegations in Paragraph 42 of the Amended Complaint.
- 43. In response to Paragraph 43 of the Amended Complaint, Blouch admits that Invacare operates in the geographic regions of North America, Asia/Pacific, and Europe, admits that the North America region is the Company's largest geographical segment by revenue, accounting for over 40% of the Company's annual revenues in 2009, 2010, and 2011, and denies the remaining allegations.
- 44. In response to Paragraph 44 of the Amended Complaint, Blouch states that Invacare maintained at times three business categories for the North America region and admits the remaining allegations.

- 45. In response to Paragraph 45 of the Amended Complaint, Blouch denies that manual wheelchairs, powered wheelchairs, scooters and similar products account for 66% of Invacare's sales, and admits the remaining allegations.
- 46. In response to Paragraph 46 of the Amended Complaint, Blouch admits that many of Invacare's device design specifications for powered wheelchairs and for powered beds are developed at its Corporate Headquarters, admits that Invacare's Corporate Headquarters also handles complaints and certain other aspects of the Company's Quality Assurance program, and denies the remaining allegations.

# B. Invacare Products Are Strictly Regulated

- 47. In response to Paragraph 47 of the Amended Complaint, Blouch states that Invacare's SEC filings speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 47 is inconsistent with the Company's SEC filings, it is denied. Blouch further states that the remaining allegations constitute legal conclusions to which a response is neither warranted nor appropriate.
- 48. In response to Paragraph 48 of the Amended Complaint, Blouch states that the Act speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 48 is inconsistent with the Act, it is denied.
- 49. In response to Paragraph 49 of the Amended Complaint, Blouch states that the Act speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 49 is inconsistent with the Act, it is denied.
- 50. In response to Paragraph 50 of the Amended Complaint, Blouch states that the FDA's regulations speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 50 is inconsistent with the FDA's regulations, it is denied.

- 51. In response to Paragraph 51 of the Amended Complaint, Blouch states that the annual reports speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 51 is inconsistent with the Invacare's annual reports, it is denied.
- 52. In response to Paragraph 52 of the Amended Complaint, Blouch states that the annual reports speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 52 is inconsistent with the Invacare's annual reports, it is denied.
- 53. In response to Paragraph 53 of the Amended Complaint, Blouch states that the FDA Investigations Operations Manual 2009 speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 53 is inconsistent with the FDA Investigations Operations Manual 2009, it is denied. Blouch denies the remaining allegations for want of knowledge or information sufficient to form a belief as to their truth.
- 54. In response to Paragraph 54 of the Amended Complaint, Blouch states that FDA Field Management Directive No. 120 speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 54 is inconsistent with FDA Field Management Directive No. 120, it is denied. Blouch denies the remaining allegations for want of knowledge or information sufficient to form a belief as to their truth.
- 55. Blouch denies the allegations in Paragraph 55 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 56. In response to Paragraph 56 of the Amended Complaint, Blouch states that the U.S. Food and Drug Administration, Regulatory Procedures Manual speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 56 is inconsistent with the U.S. Food and Drug Administration, Regulatory Procedures Manual, it is

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denied. Blouch denies the remaining allegations for want of knowledge or information sufficient to form a belief as to their truth.

- 57. Blouch denies the allegations in Paragraph 57 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 58. In response to Paragraph 58 of the Amended Complaint, Blouch states that the FDA guidelines speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 58 is inconsistent with the FDA guidelines, it is denied. Blouch denies the remaining allegations for want of knowledge or information sufficient to form a belief as to their truth.

# C. The U.S. Government's Complaint For A Permanent Injunction

- 59. In response to Paragraph 59 of the Amended Complaint, Blouch admits that on December 20, 2012, the United States filed a Complaint for Permanent Injunction against Invacare, Blouch, and Clines (the "FDA Complaint"). Blouch states that the FDA Complaint speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 59 is inconsistent with the FDA Complaint, it is denied.
- 60. In response to Paragraph 60, including Footnote 2, of the Amended Complaint, Blouch admits the FDA inspected Invacare's Corporate facility in September 2002, October 2004, April 2005 and December 2008, and inspected the Taylor Street facility in March 2003 and December 2008, and admits that the FDA issued certain Form 483s to Invacare. Blouch states that said Form 483s and the FDA Complaint speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 60 is inconsistent with said Form 483s and the FDA Complaint, it is denied. Blouch denies the remaining allegations.

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61. In response to Paragraph 61 of the Amended Complaint, Blouch states that the FDA Complaint and related FDA documentation speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 61 is inconsistent with the FDA Complaint and related FDA documentation, it is denied. Blouch denies the remaining allegations.

## 1. Invacare Sold Adulterated Products

- 62. In response to Paragraph 62 of the Amended Complaint, Blouch states that the FDA Complaint speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 62 is inconsistent with the FDA Complaint, it is denied.
- 63. In response to Paragraph 63 of the Amended Complaint, Blouch states that the FDA Complaint speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 63 is inconsistent with the FDA Complaint, it is denied.
  - 64. Blouch denies the allegations in Paragraph 64 of the Amended Complaint.
- 65. Blouch denies the allegations in Paragraph 65 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 66. Blouch denies the allegations in Paragraph 66 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 67. In response to Paragraph 67, including Footnote 3, of the Amended Complaint, Blouch states that the FDA Complaint and the Act speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 67 is inconsistent with the FDA Complaint or the Act, it is denied.

- 68. In response to Paragraph 68 of the Amended Complaint, Blouch admits that CAPA is a concept within GMP, and denies the allegations relating to CW1 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.
- 69. In response to Paragraph 69 of the Amended Complaint, Blouch admits that Invacare receives product returns and states that Invacare has a procedure for processing said returns. Blouch further denies the allegations relating to CW1 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.
- 70. In response to Paragraph 70 of the Amended Complaint, Blouch denies the allegations relating to CW1 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.
- 71. In response to Paragraph 71 of the Amended Complaint, Blouch denies the allegations relating to CW1 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.

## 2. <u>Invacare Sold Misbranded Devices</u>

- 72. In response to Paragraph 72 of the Amended Complaint, Blouch states that the FDA Complaint and the FDCA speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 72 is inconsistent with the FDA Complaint or the FDCA, it is denied.
- 73. In response to Paragraph 73 of the Amended Complaint, Blouch denies the allegations relating to CW1 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.

# 3. <u>Invacare Repeatedly Violated Good Manufacturing Practices</u>

- 74. In response to Paragraph 74 of the Amended Complaint, Blouch states that the FDA Complaint speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 74 is inconsistent with the FDA Complaint, it is denied.
- 75. Blouch denies the allegations in the first sentence of Paragraph 75 of the Amended Complaint and denies the remaining allegations for want of knowledge or information sufficient to form a belief as to their truth.
- 76. In response to Paragraph 76 of the Amended Complaint, Blouch denies the allegations relating to CW2 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.
- 77. In response to Paragraph 77 of the Amended Complaint, Blouch denies the allegations relating to CW5 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.
- 78. In response to Paragraph 78 of the Amended Complaint, Blouch admits that, in 2012, after the FDA requested that the Company enter into a consent decree, Invacare created cages made of chain-link fence for defective parts at certain departments within the Taylor Street Facility and denies the allegations relating to CW5 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.
- 79. Blouch denies the allegations in Paragraph 79 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 80. In response to Paragraph 80 of the Amended Complaint, Blouch denies the allegations relating to CW6 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth and denies the remaining allegations.

- 81. In response to Paragraph 81 of the Amended Complaint, Blouch denies the allegations relating to CW7 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.
- 82. In response to Paragraph 82 of the Amended Complaint, Blouch denies the allegations relating to CW7 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.
- 83. Blouch denies the allegations in Paragraph 83 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 84. In response to Paragraph 84 of the Amended Complaint, Blouch denies the allegations relating to CW8 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.
- 85. In response to Paragraph 85 of the Amended Complaint, Blouch denies the allegations relating to CW8 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.
- 86. In response to Paragraph 86 of the Amended Complaint, Blouch denies the allegations relating to CW8 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.
- 87. In response to Paragraph 87 of the Amended Complaint, Blouch denies the allegations relating to CW8 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.
- 88. In response to Paragraph 88 of the Amended Complaint, Blouch denies the allegations relating to CW8 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.

89. Blouch denies the allegations in Paragraph 89 of the Amended Complaint.

# D. <u>Defendants Repeatedly Violated The FDCA And Failed To Take</u> <u>Appropriate Corrective Action Prior To And Throughout The Class Period</u>

- 90. In response to Paragraph 90 of the Amended Complaint, Blouch admits that the FDA inspected the Company's Sanford Facility in January 1996 and issued a Warning Letter in May 1996 (the "May 1996 Warning Letter"). Blouch states that the May 1996 Warning Letter speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 90 is inconsistent with the May 1996 Warning Letter, it is denied.
- 91. In response to Paragraph 91 of the Amended Complaint, Blouch admits that the FDA inspected the Company's Sanford Facility on July 22, 1998 and issued a Warning Letter on August 20, 1998 (the "August 1998 Warning Letter"). Blouch states that the August 1998 Warning Letter speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 91 is inconsistent with the August 1998 Warning Letter, it is denied.
- 92. In response to Paragraph 92 of the Amended Complaint, Blouch admits that the FDA inspected the Company's Taylor Street Facility, Cleveland Street Facility, and Corporate Headquarters in May 2003 and issued a Warning Letter on August 26, 2003 (the "August 2003 Warning Letter"). Blouch states that the August 2003 Warning Letter speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 92 is inconsistent with the August 2003 Warning Letter, it is denied.
- 93. In response to Paragraph 93 of the Amended Complaint, Blouch admits that the FDA inspected the Company's Corporate Headquarters and Taylor Street Facility in December 2008 and issued a letter to Invacare on November 29, 2009 (the "November 2009 Letter").

Blouch states that the November 2009 Letter speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 93 is inconsistent with the November 2009 Letter, it is denied.

- 94. In response to Paragraph 94 of the Amended Complaint, Blouch admits that the FDA inspected the Company's Sanford, Florida facility between August 2, 2010 and August 18, 2010 and issued a Form 483 on August 18, 2010 (the "August 18, 2010 Form 483"). Blouch states that the August 18, 2010 Form 483 speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 94 is inconsistent with the August 18, 2010 Form 483, it is denied.
- 95. In response to Paragraph 95 of the Amended Complaint, Blouch states that the August 18, 2010 Form 483 speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 95 is inconsistent with the August 18, 2010 Form 483, it is denied.
- 96. In response to Paragraph 96 of the Amended Complaint, Blouch admits that the FDA issued a Warning Letter to Invacare on December 15, 2010 (the "December 2010 Warning Letter"). Blouch states that the December 2010 Warning Letter speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 96 is inconsistent with the December 2010 Warning Letter, it is denied.
- 97. In response to Paragraph 97 of the Amended Complaint, Blouch states that the December 2010 Warning Letter speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 97 is inconsistent with the December 2010 Warning Letter, it is denied.

- 98. In response to Paragraph 98 of the Amended Complaint, Blouch states that the December 2010 Warning Letter speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 98 is inconsistent with the December 2010 Warning Letter, it is denied.
- 99. In response to Paragraph 99 of the Amended Complaint, Blouch states that the December 2010 Warning Letter speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 99 is inconsistent with the December 2010 Warning Letter, it is denied.
- 100. In response to Paragraph 100 of the Amended Complaint, Blouch states that the May 1996, August 1998, August 2003, and December 2010 Warning Letters speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 100 is inconsistent with the May 1996, August 1998, August 2003, and December 2010 Warning Letters, it is denied. Blouch denies all remaining allegations.
- 101. In response to Paragraph 101 of the Amended Complaint, Blouch admits that Invacare received two Form 483s on December 17, 2010 (the "December 17, 2010 Form 483s"). Blouch states that the December 17, 2010 Form 483s speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 101 is inconsistent with the December 17, 2010 Form 483s, it is denied.
- 102. In response to Paragraph 102 of the Amended Complaint, Blouch states that the December 17, 2010 Form 483s and the May 1996, August 1998, August 2003, and December 2010 Warning Letters speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 102 is inconsistent with the December 17, 2010 Form 483s and the May 1996, August 1998, August 2003, and December 2010 Warning Letters, it is denied.

- 103. In response to Paragraph 103 of the Amended Complaint, Blouch admits that the FDA released a copy of the December 2010 Warning Letter on January 4, 2011, admits that Invacare common stock decline from \$30.67 per share on January 3, 2011, to close at \$29.29 per share on January 4, 2011, and denies the remaining allegations.
- 104. In response to Paragraph 104 of the Amended Complaint, Blouch admits that the FDA inspected Invacare's Corporate Headquarters and the Taylor Street Facility in July and August 2011 and states that, following said inspections, the FDA issued two Form 483s relating Invacare's Corporate Headquarters and the Taylor Street Facility on August 8, 2011 (the "August 8, 2011 Form 483s"). Blouch states that the August 8, 2011 Form 483s speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 104 is inconsistent with the August 8, 2011 Form 483s, it is denied.
- 105. In response to Paragraph 105 of the Amended Complaint, Blouch states that the August 8, 2011 Form 483s speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 105 is inconsistent with the August 8, 2011 Form 483s, it is denied.
- 106. In response to Paragraph 106 of the Amended Complaint, Blouch states that the August 8, 2011 Form 483s speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 106 is inconsistent with the August 8, 2011 Form 483s, it is denied.
- 107. In response to Paragraph 107 of the Amended Complaint, Blouch states that the August 8, 2011 Form 483s speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 107 is inconsistent with the August 8, 2011 Form 483s, it is denied.

- 108. In response to Paragraph 108 of the Amended Complaint, Blouch states that the August 8, 2011 Form 483s speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 108 is inconsistent with the August 8, 2011 Form 483s, it is denied. Blouch denies the remaining allegations.
- 109. In response to Paragraph 109 of the Amended Complaint, Blouch admits that representatives of Invacare attended a regulatory meeting with representatives from the FDA's Center for Devices and Radiological Health and Cincinnati District Office on October 24, 2011 and denies the remaining allegations.
- 110. In response to Paragraph 110 of the Amended Complaint, Blouch admits that Invacare issued a press release on October 27, 2011 (the "October 27, 2011 Press Release"). Blouch states that the October 27, 2011 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 110 is inconsistent with the October 27, 2011 Press Release, it is denied. Blouch denies the remaining allegations.
- 111. In response to Paragraph 111 of the Amended Complaint, Blouch admits that on November 8, 2011, Invacare disclosed that it had received Form 483s in connection with 2010 and 2011 inspections of the Company's Corporate Headquarters and the Taylor Street Facility, admits that Invacare told investors that it was "working with the FDA to resolve the inspectional observations identified in the warning letter and in the FDA-483s for the Sites," and denies the remaining allegations.
- 112. In response to Paragraph 112 of the Amended Complaint, Blouch states that the December 8, 2011 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 112 is inconsistent with the December 8, 2011 Press Release, it is denied.

113. In response to Paragraph 113 of the Amended Complaint, Blouch admits that stock went from \$20.58 per share on December 7, 2011 to close at \$14.70 per share on December 8, 2011, dropping \$5.88 per share, and denies the remaining allegations.

## **E.** Post-Class Period Events

- Invacare has incurred "quality and regulatory costs" related to the Consent Decree, admits that delaying new product development has "had a ripple effect on the performance of the organization," and admits that Invacare reported to shareholders that "the limitations in the consent decree had, and likely will continue to have, a material adverse effect on the company's business, financial condition and results of operations." Blouch denies the remaining allegations.
- 115. In response to Paragraph 115 of the Amended Complaint, Blouch admits that Invacare announced that the FDA intended to seek the Consent Decree in December 2011, admits that Invacare negotiated the terms of the Consent Decree, admits that Invacare has taken steps to bring the Company into regulatory compliance, admits that Invacare continues to operate under the terms of the Consent Decree, and denies the remaining allegations.
- 116. In response to Paragraph 116 of the Amended Complaint, Blouch states that the December 9, 2011 *Chronicle-Telegram* article titled, "FDA May Idle Invacare Plant" speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 116 is inconsistent with the article, it is denied.
- 117. In response to Paragraph 117 of the Amended Complaint, Blouch admits that, on January 4, 2012, the Company announced that it had hired Doug Uelmen ("Uelmen") as Invacare's new Senior Vice President of Quality Assurance and Regulatory Affairs, admits that Uelmen joined the Company in late December, 2012, admits that Uelmen was hired to help {02648654.DOCX;5}

Invacare work through its quality control issues with the federal government, and admits that Uelman was experienced in the area of quality-control and regulatory matters. Blouch further states that the January 6, 2012 *Chronicle-Telegram* article speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 117 is inconsistent with the article, it is denied.

- 118. In response to Paragraph 118 of the Amended Complaint, Blouch admits that Invacare filed with the SEC its Annual Report on Form 10-K for 2011 on March 26, 2012 ("2011 Annual Report"). Blouch states that the 2011 Annual Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 118 is inconsistent with the 2011 Annual Report, it is denied.
- 119. In response to Paragraph 119 of the Amended Complaint, Blouch states that the 2011 Annual Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 119 is inconsistent with the 2011 Annual Report, it is denied.
- 120. In response to Paragraph 120 of the Amended Complaint, Blouch admits that Invacare issued a press release and Form 8-K on April 26, 2012 (the "April 26, 2012 Press Release and Form 8-K"). Blouch states that the April 26, 2012 Press Release and Form 8-K speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 120 is inconsistent with the May 7, 2012 Form 10-Q, it is denied.
- 121. In response to Paragraph 121 of the Amended Complaint, Blouch admits that Invacare hosted an earnings conference call with investors on April 26, 2012 (the "April 26, 2012 Earnings Call"), admits that he made statements during the April 26, 2012 Earnings Call, admits that Lead Plaintiff has quoted some, but not all, of the statements made by him during the

April 26, 2012 Earnings Call, and denies the remaining allegations to the extent they are inconsistent with statements made by him during the April 26, 2012 Earnings Call.

- 122. In response to Paragraph 122 of the Amended Complaint, Blouch admits that Invacare filed its Form 10-Q for the first quarter of 2012 on May 7, 2012 (the "1st Quarter 2012 10-O"). Blouch states that the 1st Quarter 2012 10-O speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 122 is inconsistent with the 1st Quarter 2012 10-Q, it is denied.
- In response to Paragraph 123 of the Amended Complaint, Blouch admits that he attended the Bank of America Merrill Lynch 2012 Health Care Conference in Las Vegas on May 15, 2012 (the "Conference"), admits that he made statements regarding the proposed consent decree during the Conference, admits that Lead Plaintiff has quoted some, but not all, of the statements made by him at the Conference, and denies the remaining allegations to the extent they are inconsistent with the statements made by him at the Conference.
- Blouch denies the first sentence of Paragraph 124 of the Amended Complaint and 124. denies the second sentence for want of knowledge or information sufficient to form a belief as to their truth and denies the remaining allegations.
- In response to Paragraph 125 of the Amended Complaint, Blouch admits that Invacare issued a press release and Form 8-K on July 26, 2012 (the "July 26, 2012 Press Release and Form 8-K"). Blouch states that the July 26, 2012 Press Release and Form 8-K speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 125 is inconsistent with the July 26, 2012 Press Release and Form 8-K, it is denied.
- In response to Paragraph 126 of the Amended Complaint, Blouch states that the 126. September 22, 2012 Chronicle-Telegram article speaks for itself and, therefore, no response is 23

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required. To the extent any allegation set forth in Paragraph 126 is inconsistent with the article, it is denied.

- 127. Blouch denies the allegations in Paragraph 127 of the Amended Complaint.
- 128. In response to Paragraph 128 of the Amended Complaint, Blouch admits that Invacare issued a press release and Form 8-K on October 25, 2012 (the "October 25, 2012 Press Release and Form 8-K"). Blouch states that the October 25, 2012 Press Release and Form 8-K speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 128 is inconsistent with the October 25, 2012 Press Release and Form 8-K, it is denied.
- 129. In response to Paragraph 129 of the Amended Complaint, Blouch admits that the FDA issued a press release regarding the Consent Decree with Invacare on December 20, 2012 (the "December 20, 2012 Press Release"). Blouch states that the December 20, 2012 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 129 is inconsistent with the December 20, 2012 Press Release, it is denied.
- 130. In response to Paragraph 130 of the Amended Complaint, Blouch admits that he signed the Consent Decree. Blouch states that the Consent Decree speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 130 is inconsistent with the Consent Decree, it is denied.
- 131. In response to Paragraph 131 of the Amended Complaint, Blouch states that the Consent Decree speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 131 is inconsistent with the Consent Decree, it is denied.
- 132. In response to Paragraph 132 of the Amended Complaint, Blouch states that the December 21, 2012, *The Plain Dealer* article speaks for itself and, therefore, no response is {02648654.DOCX;5}

required. To the extent any allegation set forth in Paragraph 132 is inconsistent with the article, it is denied.

- 133. In response to Paragraph 133 of the Amended Complaint, Blouch admits that Invacare issued a press release on December 27, 2012 (the "December 27, 2012 Press Release"). Blouch states that the December 27, 2012 Press Release and *Chronicle-Telegram* article speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 133 is inconsistent with the December 27, 2012 Press Release and *Chronicle-Telegram* article, it is denied.
- 134. In response to Paragraph 134 of the Amended Complaint, Blouch admits that Invacare filed with the SEC its Annual Report on Form 10-K for 2012 on March 15, 2013 (the "2012 Annual Report"), which was accompanied with a letter to shareholders from Defendants Blouch and Mixon. Blouch states that the referenced letter speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 134 is inconsistent with the referenced letter, it is denied.
- 135. In response to Paragraph 135 of the Amended Complaint, Blouch states that the referenced letter speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 135 is inconsistent with the referenced letter, it is denied.
- 136. In response to Paragraph 136 of the Amended Complaint, Blouch states that the 2012 Annual Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 136 is inconsistent with the 2012 Annual Report, it is denied.
- 137. In response to Paragraph 137 of the Amended Complaint, Blouch states that the April 9, 2013 *Chronicle-Telegram* article speaks for itself and, therefore, no response is required.

To the extent any allegation set forth in Paragraph 137 is inconsistent with the April 9, 2013 *Chronicle-Telegram* article, it is denied.

- 138. In response to Paragraph 138 of the Amended Complaint, Blouch admits that Invacare issued a press release on April 25, 2013, reporting its financial results for the first quarter of 2013 (the "April 25, 2013 Press Release"). Blouch states that the April 25, 2013 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 138 is inconsistent with the April 25, 2013 Press Release, it is denied.
- 139. In response to Paragraph 139 of the Amended Complaint, Blouch admits that Invacare hosted an earnings conference call with investors on April 25, 2013 (the "April 25, 2013 Earnings Call"), admits that Gudbranson made statements during the April 25, 2013 Earnings Call, admits that Lead Plaintiff has quoted some, but not all, of the statements made by Gudbranson during the April 25, 2013 Earnings Call, and denies the remaining allegations to the extent they are inconsistent with the statements made by Gudbranson during the April 25, 2013 Earnings Call.
- 140. In response to Paragraph 140 of the Amended Complaint, Blouch admits that Invacare announced on May 14, 2013 that the FDA had approved the first of the three audits required under the terms of the Consent Decree, allowing the Company to resume certain limited production activities at the Taylor Street Facility. Blouch further states that HME News article speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 140 is inconsistent with the HME News article, it is denied. Blouch denies the remaining allegations in Paragraph 140 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.

- 141. In response to Paragraph 141 of the Amended Complaint, Blouch admits that Invacare issued a press release on July 16, 2013 (the "July 16, 2013 Press Release"). Blouch states that the July 16, 2013 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 141 is inconsistent with the July 16, 2013 Press Release, it is denied.
- 142. In response to Paragraph 142 of the Amended Complaint, Blouch admits that Invacare issued a press release and Form 8-K on July 25, 2013 (the "July 25, 2013 Press Release and Form 8-K"). Blouch states that the July 25, 2013 Press Release and Form 8-K speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 142 is inconsistent with the July 25, 2013 Press Release and Form 8-K, it is denied.
- 143. In response to Paragraph 143 of the Amended Complaint, Blouch states that the July 27, 2013 *Chronicle-Telegram* article speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 143 is inconsistent with the July 27, 2013 *Chronicle-Telegram* article, it is denied.
- 144. In response to Paragraph 144 of the Amended Complaint, Blouch admits that Invacare issued a press release and Form 8-K on October 24, 2013 (the "October 24, 2013 Press Release and Form 8-K"). Blouch states that the October 24, 2013 Press Release and Form 8-K speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 144 is inconsistent with the October 24, 2013 Press Release and Form 8-K, it is denied.
- 145. In response to Paragraph 145 of the Amended Complaint, Blouch states that the October 24, 2013 Press Release speaks for itself and, therefore, no response is required. To the

extent any allegation set forth in Paragraph 145 is inconsistent with the October 24, 2013 Press Release, it is denied.

146. In response to Paragraph 146 of the Amended Complaint, Blouch states that the October 24, 2013 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 146 is inconsistent with the October 24, 2013 Press Release, it is denied. With respect to Footnote 5, Blouch admits that on August 23, 2011, the City of Lansing Police and Fire filed a shareholder derivative action in the Court of Common Pleas in Lorain County, Ohio against the Company's board of directors and the Company nominally (the "City of Lansing Lawsuit"), admits that on February 2, 2012 Colleen Witmer filed a shareholder derivative lawsuit in the Northern District of Ohio against certain directors and the Company nominally (the "Witmer Lawsuit"), and admits that the City of Lansing Lawsuit and Witmer Lawsuit were settled in July of 2012. Blouch states that the City of Lansing Lawsuit and Witmer Lawsuit speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 146 is inconsistent with the City of Lansing Lawsuit and Witmer Lawsuit, it is denied.

# VII. <u>DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS</u> <u>AND OMISSIONS</u>

- 147. Blouch denies the allegations in Paragraph 147 of the Amended Complaint.
- 148. Blouch denies the allegations in Paragraph 148 of the Amended Complaint.
- 149. Blouch denies the allegations in Paragraph 149 of the Amended Complaint.
- 150. Blouch denies the allegations in Paragraph 150 of the Amended Complaint.
- 151. Blouch denies the allegations in Paragraph 151 of the Amended Complaint.

- 152. In response to Paragraph 152 of the Amended Complaint, Blouch admits that Invacare hired a Chief Compliance Officer, admits that the first Chief Compliance Officer hired by Invacare resigned, denies all allegations relating to statements made by a confidential witness for want of knowledge or information sufficient to form a belief as to their truth, and denies the remaining allegations.
- 153. In response to Paragraph 153 of the Amended Complaint, Blouch admits that Invacare has expended at least \$40 million regulatory compliance costs since the end of the Class Period, including approximately \$5 million in the first quarter of 2013. Blouch denies the remaining allegations.
- 154. In response to Paragraph 154 of the Amended Complaint, Blouch admits that Invacare devotes internal resources to remediate compliance deficiencies, admits that Invacare works to ensure full QSR compliance across the organization, and denies the remaining allegations.
- 155. In response to Paragraph 155 of the Amended Complaint, Blouch denies that the statements identified in bold, italics are materially false and misleading statements and omissions.

### A. 2008 Annual Report

156. In response to Paragraph 156 of the Amended Complaint, Blouch admits that Invacare filed with the SEC its Annual Report on Form 10-K for 2008 on February 27, 2009 ("2008 Annual Report"). Blouch states that the 2008 Annual Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 156 is inconsistent with the 2008 Annual Report, it is denied.

- 157. In response to Paragraph 157 of the Amended Complaint, Blouch states that the 2008 Annual Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 157 is inconsistent with the 2008 Annual Report, it is denied.
- 158. In response to Paragraph 158 of the Amended Complaint, Blouch states that the 2008 Annual Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 158 is inconsistent with the 2008 Annual Report, it is denied.
- 159. In response to Paragraph 159 of the Amended Complaint, Blouch states that the 2008 Annual Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 159 is inconsistent with the 2008 Annual Report, it is denied.
- 160. In response to Paragraph 160 of the Amended Complaint, including Footnote 7, Blouch states that the 2008 Annual Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 160 is inconsistent with the 2008 Annual Report, it is denied.

## B. First Quarter 2009

- 161. In response to Paragraph 161 of the Amended Complaint, Blouch admits that Invacare issued a press release on April 23, 2009 (the "April 23, 2009 Press Release"). Blouch states that the April 23, 2009 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 161 is inconsistent with the April 23, 2009 Press Release, it is denied.
- 162. In response to Paragraph 162 of the Amended Complaint, Blouch states that the Natixis report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 162 is inconsistent with the Natixis report, it is denied.

- 163. In response to Paragraph 163 of the Amended Complaint, Blouch states that the Natixis report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 163 is inconsistent with the Natixis report, it is denied.
- 164. In response to Paragraph 164 of the Amended Complaint, Blouch admits that Invacare filed its Form 10-Q for the first quarter of 2009 with the SEC on May 7, 2009 (the "1st Quarter 2009 10-Q"). Blouch states that the 1st Quarter 2009 10-Q speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 164 is inconsistent with 1st Quarter 2009 10-Q, it is denied.

# C. Second Quarter 2009

- 165. In response to Paragraph 165 of the Amended Complaint, Blouch admits that Invacare issued a press release on July 23, 2009 (the "July 23, 2009 Press Release"). Blouch states that the July 23, 2009 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 165 is inconsistent with the July 23, 2009 Press Release, it is denied.
- 166. In response to Paragraph 166 of the Amended Complaint, Blouch admits that Invacare filed its Form 10-Q for the second quarter of 2009 with the SEC on August 6, 2009 (the "2nd Quarter 2009 10-Q"). Blouch states that the 2nd Quarter 2009 10-Q speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 166 is inconsistent with 2nd Quarter 2009 10-Q, it is denied.

#### D. Third Quarter 2009

167. In response to Paragraph 167 of the Amended Complaint, Blouch admits that Invacare issued a press release on October 22, 2009 (the "October 22, 2009 Press Release").

Blouch states that the October 22, 2009 Press Release speaks for itself and, therefore, no 

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response is required. To the extent any allegation set forth in Paragraph 167 is inconsistent with the October 22, 2009 Press Release, it is denied.

- 168. Blouch denies the allegations in Paragraph 168 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 169. In response to Paragraph 169 of the Amended Complaint, Blouch admits that Invacare filed its Form 10-Q for the third quarter of 2009 with the SEC on November 5, 2009 (the "3rd Quarter 2009 10-Q"). Blouch states that the 3rd Quarter 2009 10-Q speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 169 is inconsistent with 3rd Quarter 2009 10-Q, it is denied.
- 170. In response to Paragraph 170 of the Amended Complaint, Blouch admits that the FDA inspected Invacare's Corporate Headquarters in December 2008. Blouch states the FDA Complaint and the Form 483s issued by the FDA speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 170 is inconsistent with the FDA Complaint and the Form 483s issued by the FDA, it is denied. Further, Blouch denies the statements made by CW5 and other former Invacare employees for want of knowledge or information sufficient to form a belief as to their truth, and denies the remaining allegations.

#### E. 2009 Annual Report

171. In response to Paragraph 171 of the Amended Complaint, Blouch admits that Invacare issued a press release on February 4, 2010 (the "February 4, 2010 Press Release"). Blouch states that the February 4, 2010 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 171 is inconsistent with the February 4, 2010 Press Release, it is denied.

- 172. In response to Paragraph 172 of the Amended Complaint, Blouch admits that Invacare filed with the SEC its Annual Report on Form 10-K for 2008 on February 26, 2010 ("2009 Annual Report"). Blouch states that the 2009 Annual Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 172 is inconsistent with the 2009 Annual Report, it is denied.
- 173. In response to Paragraph 173 of the Amended Complaint, Blouch states that the 2009 Annual Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 173 is inconsistent with the 2009 Annual Report, it is denied.
- 174. In response to Paragraph 174 of the Amended Complaint, Blouch states that the 2009 Annual Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 174 is inconsistent with the 2009 Annual Report, it is denied.
- 175. In response to Paragraph 175 of the Amended Complaint, Blouch admits that the FDA inspected Invacare's Corporate Headquarters in December 2008. Blouch states the FDA Complaint, the Form 483s issued by the FDA, and the FDA's November 29, 2009 letter speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 175 is inconsistent with the FDA Complaint and the Form 483s issued by the FDA, it is denied. Further, Blouch denies the statements made by CW6 and other former Invacare employees for want of knowledge or information sufficient to form a belief as to their truth, and denies the remaining allegations.

#### F. First Quarter 2010

176. In response to Paragraph 176 of the Amended Complaint, Blouch admits that Invacare issued a press release on April 22, 2010 (the "April 22, 2010 Press Release"). Blouch states that the April 22, 2010 Press Release speaks for itself and, therefore, no response is 

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required. To the extent any allegation set forth in Paragraph 176 is inconsistent with the April 22, 2010 Press Release, it is denied.

177. In response to Paragraph 177 of the Amended Complaint, Blouch admits that Invacare filed its Form 10-Q for the first quarter of 2010 with the SEC on May 6, 2010 (the "1st Quarter 2010 10-Q"). Blouch states that the 1st Quarter 2010 10-Q speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 177 is inconsistent with 1st Quarter 2010 10-Q, it is denied.

## G. Second Quarter 2010

178. In response to Paragraph 178 of the Amended Complaint, Blouch admits that Invacare issued a press release on July 22, 2010 (the "July 22, 2010 Press Release"). Blouch states that the July 22, 2010 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 178 is inconsistent with the July 22, 2010 Press Release, it is denied.

179. In response to Paragraph 179 of the Amended Complaint, Blouch admits that Invacare filed its Form 10-Q for the first quarter of 2010 with the SEC on August 6, 2010 (the "2nd Quarter 2010 10-Q"). Blouch states that the 2nd Quarter 2010 10-Q speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 179 is inconsistent with 2nd Quarter 2010 10-Q, it is denied.

## H. Third Quarter 2010

180. In response to Paragraph 180 of the Amended Complaint, Blouch admits that Invacare issued a press release on October 28, 2010 (the "October 28, 2010 Press Release"). Blouch states that the October 28, 2010 Press Release speaks for itself and, therefore, no

response is required. To the extent any allegation set forth in Paragraph 180 is inconsistent with the October 28, 2010 Press Release, it is denied.

- 181. In response to Paragraph 181 of the Amended Complaint, Blouch states that the October 28, 2010 *The Plain Dealer* article speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 181 is inconsistent with the October 28, 2010 *The Plain Dealer* article, it is denied.
- 182. In response to Paragraph 182 of the Amended Complaint, Blouch admits that Invacare filed its Form 10-Q for the first quarter of 2010 with the SEC on November 5, 2010 (the "3rd Quarter 2010 10-Q"). Blouch states that the 3rd Quarter 2010 10-Q speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 182 is inconsistent with 3rd Quarter 2010 10-Q, it is denied.
- 183. In response to Paragraph 183 of the Amended Complaint, Blouch admits that, on August 18, 2010, the FDA concluded an inspection of the Company's Sanford Facility and issued a Form 483 (the "August 18, 2010 Form 483"). Blouch states that the August 18, 2010 Form 483 speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 183 is inconsistent with the August 18, 2010 Form 483, it is denied. Further, Blouch denies the statements made by CW7 and other former Invacare employees for want of knowledge or information sufficient to form a belief as to their truth, and denies the remaining allegations.

## I. Defendants' Statements Regarding The FDA Warning Letter

184. In response to Paragraph 184 of the Amended Complaint, Blouch admits that the FDA released a copy of the December 15, 2010 Warning Letter on January 4, 2011. Blouch states that the December 15, 2010 Warning Letter speaks for itself and, therefore, no response is 

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required. To the extent any allegation set forth in Paragraph 184 is inconsistent with the December 15, 2010 Warning Letter, it is denied.

- 185. In response to Paragraph 185 of the Amended Complaint, Blouch states that the December 15, 2010 Warning Letter speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 185 is inconsistent with the December 15, 2010 Warning Letter, it is denied.
- 186. In response to Paragraph 186 of the Amended Complaint, Blouch states that the December 15, 2010 Warning Letter speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 186 is inconsistent with the December 15, 2010 Warning Letter, it is denied.
- 187. In response to Paragraph 187 of the Amended Complaint, Blouch admits that Invacare issued a press release on January 4, 2011 (the "January 4, 2011 Press Release"). Blouch states that the January 4, 2011 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 187 is inconsistent with the January 4, 2011 Press Release, it is denied.
- 188. In response to Paragraph 188 of the Amended Complaint, Blouch admits that the FDA disclosed the December 2010 Warning Letter on January 4, 2011, admits that the price of Invacare stock declined from \$30.67 per share on January 3, 2011, to close at \$29.29 per share on January 4, 2011, and denies the remaining allegations.
- 189. In response to Paragraph 189 of the Amended Complaint, Blouch states that the January 5, 2011 CL King report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 189 is inconsistent with the January 5, 2011 CL King report, it is denied.

- 190. In response to Paragraph 190 of the Amended Complaint, Blouch admits that Invacare published a "Message from CEO Regarding FDA Letter" on January 5, 2011 (the "January 5, 2011 Message from CEO"). Blouch states that the January 5, 2011 Message from CEO speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 190 is inconsistent with the January 5, 2011 Message from CEO, it is denied.
- 191. In response to Paragraph 191 of the Amended Complaint, Blouch admits that Invacare published a "Frequently Asked Questions" section on its website addressing the December 2010 Warning Letter ("Frequently Asked Questions"). Blouch states that the Frequently Asked Questions speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 191 is inconsistent with the Frequently Asked Questions, it is denied.
- 192. In response to Paragraph 192 of the Amended Complaint, Blouch states that Invacare's website speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 192 is inconsistent with Invacare's website, it is denied.
- 193. In response to Paragraph 193 of the Amended Complaint, Blouch states that the January 5, 2011 Associated Press article speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 193 is inconsistent with the January 5, 2011 Associated Press article, it is denied.
  - 194. Blouch denies the allegations in Paragraph 194 of the Amended Complaint.
- 195. In response to Paragraph 195 of the Amended Complaint, Blouch admits that the FDA conducted inspections of Corporate Headquarters and the Taylor Street Facility between August 11, 2010 and December 17, 2010 and issued two Form 483s on December 17, 2010 (the "December 17, 2010 Form 483s"). Blouch states that the December 17, 2010 Form 483s speak

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for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 195 is inconsistent with the December 17, 2010 Form 483s, it is denied. Blouch further denies the remaining allegations.

### J. 2010 Annual Report

- 196. In response to Paragraph 196 of the Amended Complaint, Blouch admits that Invacare issued a press release on February 3, 2011 (the "February 3, 2011 Press Release"). Blouch states that the February 3, 2011 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 196 is inconsistent with the February 3, 2011 Press Release, it is denied.
- 197. In response to Paragraph 197 of the Amended Complaint, Blouch states that the February 3, 2011 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 197 is inconsistent with the February 3, 2011 Press Release, it is denied.
- 198. In response to Paragraph 198 of the Amended Complaint, Blouch admits that Invacare hosted an earnings conference call with investors on February 3, 2011 (the "February 3, 2011 Earnings Call"), admits that he made statements during the February 3, 2011 Earnings Call, and denies the remaining allegations to the extent they are inconsistent with the statements made by him during the February 3, 2011 Earnings Call.
- 199. In response to Paragraph 199 of the Amended Complaint, Blouch states that the WJB Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 199 is inconsistent with the WJB Report, it is denied. Blouch denies the remaining allegations in Paragraph 199 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.

- 200. In response to Paragraph 200 of the Amended Complaint, Blouch admits that Invacare filed with the SEC its Annual Report on Form 10-K for 2010 on February 25, 2011 ("2010 Annual Report"). Blouch states that the 2010 Annual Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 200 is inconsistent with the 2010 Annual Report, it is denied.
- 201. In response to Paragraph 201 of the Amended Complaint, Blouch states that the 2010 Annual Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 201 is inconsistent with the 2010 Annual Report, it is denied.
- 202. In response to Paragraph 202 of the Amended Complaint, Blouch states that the 2010 Annual Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 202 is inconsistent with the 2010 Annual Report, it is denied.
- 203. In response to Paragraph 203 of the Amended Complaint, Blouch states that the 2010 Annual Report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 203 is inconsistent with the 2010 Annual Report, it is denied.
  - 204. Blouch denies the allegations in Paragraph 204 of the Amended Complaint.
- 205. In response to Paragraph 205 of the Amended Complaint, Blouch admits that Invacare received the December 17, 2010 Form 483s from the FDA following inspections of the Company's Corporate Headquarters and the Taylor Street Facility between August 11, 2010 and December 17. Blouch states that the December 17, 2010 Form 483s speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 205 is inconsistent with said December 17, 2010 Form 483s, it is denied. Blouch denies all allegations relating to the "Medical Device Quality Systems Manual: A Small Entity Compliance Guide" for

want of knowledge or information sufficient to form a belief as to their truth and denies all remaining allegations.

206. In response to Paragraph 206 of the Amended Complaint, Blouch denies the statements made by CW7 and other former Invacare employees for want of knowledge or information sufficient to form a belief as to their truth, and denies the remaining allegations.

207. In response to Paragraph 207 of the Amended Complaint, Blouch admits that Invacare has expended at least \$40 million on regulatory compliance costs and to ensure QS Regulation compliance, and denies the remaining allegations.

208. In response to Paragraph 208 of the Amended Complaint, Blouch admits that Invacare issued a Form 8-K on March 8, 2011 (the "March 8, 2011 Form 8-K"). Blouch states that the March 8, 2011 Form 8-K speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 208 is inconsistent with the March 8, 2011 Form 8-K, it is denied. Further, Blouch states that the March 8, 2011 CL King report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 208 is inconsistent with the March 8, 2011 CL King report, it is denied. Blouch denies the remaining allegations.

# K. First Quarter 2011

209. In response to Paragraph 209 of the Amended Complaint, Blouch admits that Invacare issued a press release on April 28, 2011 (the "April 28, 2011 Press Release"). Blouch states that the April 28, 2011 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 209 is inconsistent with the April 28, 2011 Press Release, it is denied.

- 210. In response to Paragraph 210 of the Amended Complaint, Blouch states that the April 28, 2011 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 210 is inconsistent with the April 28, 2011 Press Release, it is denied.
- 211. In response to Paragraph 211 of the Amended Complaint, Blouch admits that Invacare filed its Form 10-Q for the first quarter of 2011 with the SEC on May 5, 2011 (the "1st Quarter 2011 10-Q"). Blouch states that the 1st Quarter 2011 10-Q speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 211 is inconsistent with 1st Quarter 2011 10-Q, it is denied.
- 212. In response to Paragraph 212 of the Amended Complaint, Blouch states that the 1st Quarter 2011 10-Q speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 212 is inconsistent with the 1st Quarter 2011 10-Q, it is denied.
- 213. In response to Paragraph 213 of the Amended Complaint, Blouch states that the 1st Quarter 2011 10-Q speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 213 is inconsistent with the 1st Quarter 2011 10-Q, it is denied.

# L. Second Quarter 2011

- 214. In response to Paragraph 214 of the Amended Complaint, Blouch admits that Invacare issued a press release on July 28, 2011 (the "July 28, 2011 Press Release"). Blouch states that the July 28, 2011 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 214 is inconsistent with the July 28, 2011 Press Release, it is denied.
- 215. In response to Paragraph 215 of the Amended Complaint, Blouch admits that Invacare hosted an earnings conference call with investors on July 28, 2011 (the "July 28, 2011 {02648654.DOCX;5} 41

Earnings Call"), admits that analysts asked Invacare executives questions during the July 28, 2011 Earnings Call, admits that Lead Plaintiff has quoted some, but not all, of the statements made by him during the July 28, 2011 Earnings Call, and denies the remaining allegations.

- 216. In response to Paragraph 216 of the Amended Complaint, Blouch admits that Invacare filed its Form 10-Q for the second quarter of 2011 with the SEC on August 8, 2011 (the "2nd Quarter 2011 10-Q"). Blouch states that the 2nd Quarter 2011 10-Q speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 216 is inconsistent with 2nd Quarter 2011 10-Q, it is denied.
- 217. In response to Paragraph 217 of the Amended Complaint, Blouch states that the 2nd Quarter 2011 10-Q speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 217 is inconsistent with 2nd Quarter 2011 10-Q, it is denied.
- 218. In response to Paragraph 218 of the Amended Complaint, Blouch states that the 2nd Quarter 2011 10-Q speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 218 is inconsistent with 2nd Quarter 2011 10-Q, it is denied.
- 219. In response to Paragraph 219 of the Amended Complaint, Blouch admits that Invacare issued a press release on August 18, 2011 (the "August 18, 2011 Press Release"). Blouch states that the August 18, 2011 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 219 is inconsistent with the August 18, 2011 Press Release, it is denied.
  - 220. Blouch denies the allegations in Paragraph 220 of the Amended Complaint.
  - 221. Blouch denies the allegations in Paragraph 221 of the Amended Complaint.

# M. Third Quarter 2011

- 222. In response to Paragraph 222 of the Amended Complaint, Blouch admits that Invacare issued a press release on October 27, 2011 (the "October 27, 2011 Press Release"). Blouch states that the October 27, 2011 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 222 is inconsistent with the October 27, 2011 Press Release, it is denied.
- 223. In response to Paragraph 223 of the Amended Complaint, Blouch admits that Invacare's stock price dropped from \$23.81 per share on October 26, 2011 to close at \$22.80 per share on October 27, 2011, a decline of 4.3% or \$1.01 per share, and denies the remaining allegations.
- 224. In response to Paragraph 224 of the Amended Complaint, Blouch admits that Invacare hosted an earnings conference call with investors on October 27, 2011 (the "October 27, 2011 Earnings Call"), admits that analysts asked Invacare executives questions during the October 27, 2011 Earnings Call, admits that Lead Plaintiff has quoted some, but not all, of the statements made by him (Blouch) during the October 27, 2011 Earnings Call, and denies the remaining allegations.
- 225. In response to Paragraph 225 of the Amended Complaint, Blouch admits that Lead Plaintiff has quoted some, but not all, of the statements made by him during the October 27, 2011 Earnings Call, and denies the remaining allegations.
- 226. In response to Paragraph 226 of the Amended Complaint, Blouch admits that Lead Plaintiff has quoted some, but not all, of the statements made by him during the October 27, 2011 Earnings Call, and denies the remaining allegations.

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- 227. In response to Paragraph 227 of the Amended Complaint, Blouch admits that Invacare hosted the October 27, 2011 Earnings Call, admits that analysts asked Invacare executives questions during the October 27, 2011 Earnings Call, admits that Lead Plaintiff has quoted some, but not all, of the statements made by him and Gudbranson during the October 27, 2011 Earnings Call, and denies the remaining allegations.
- 228. In response to Paragraph 228 of the Amended Complaint, Blouch admits that Invacare filed its Form 10-Q for the third quarter of 2011 with the SEC on November 8, 2011 (the "3rd Quarter 2011 10-Q"). Blouch states that the 3rd Quarter 2011 10-Q speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 228 is inconsistent with 3rd Quarter 2011 10-Q, it is denied.
- 229. In response to Paragraph 229 of the Amended Complaint, Blouch states that the 3rd Quarter 2011 10-Q speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 229 is inconsistent with 3rd Quarter 2011 10-Q, it is denied.
- 230. In response to Paragraph 230 of the Amended Complaint, Blouch admits that the FDA inspected Invacare's Corporate Headquarters and Taylor Street Facility between August 11, 2010 and December 17, 2010, admits that the FDA issued two Forms 483s as a result of said inspections (the "December 2010 Form 483s"), admits that the FDA issued two Forms 483s on August 8, 2011 following inspections at Invacare's Corporate Headquarters and Taylor Street Facility (the "August 8, 2011 Form 483s"), and admits that representatives of Invacare attended a regulatory meeting with representatives of the FDA's Center for Devices and Radiological Health and Cincinnati District Office on October 24, 2011. Further, Blouch states that the October 27, 2011 Press Release, the October 27, 2011 Earnings Call, 3rd Quarter 2011 10-Q, the December 2010 Warning Letter, the December 2010 Form 483s, the August 8, 2011 Form 483s,

and Invacare's communications to the FDA dated August 29, September 15, September 29, and October 28, 2011, speak for themselves and, therefore, no response is required. To the extent any allegation set forth in Paragraph 230 is inconsistent with the October 27, 2011 Press Release, the October 27, 2011 Earnings Call, 3rd Quarter 2011 10-Q, the December 2010 Warning Letter, the December 2010 Form 483s, the August 8, 2011 Form 483s. and Invacare's communications to the FDA dated August 29, September 15, September 29, and October 28, 2011, it is denied. Blouch denies the remaining allegations.

231. In response to Paragraph 231 of the Amended Complaint, Blouch admits that Invacare has expended at least \$40 million on regulatory compliance costs since the end of the Class Period, including approximately \$5 million in the first quarter of 2013. Further, Blouch states that the Company's Form 10-Q for the third quarter of 2013 speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 231 is inconsistent with the Company's Form 10-Q for the third quarter of 2013, it is denied. Blouch denies the remaining allegations.

# VIII. LOSS CAUSATION

- 232. Blouch denies the allegations in Paragraph 232 of the Amended Complaint.
- 233. Blouch denies the allegations in Paragraph 233 of the Amended Complaint.
- 234. Blouch denies the allegations in Paragraph 234 of the Amended Complaint.
- 235. In response to Paragraph 235 of the Amended Complaint, Blouch admits that Invacare's stock price declined from \$30.67 per share on January 3, 2011 to close at \$29.29 per share on January 4, 2011. Blouch states that the December 15, 2010 Warning Letter speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph

235 is inconsistent with the December 15, 2010 Warning Letter, it is denied. Blouch denies the remaining allegations in Paragraph 235 of the Amended Complaint.

- 236. In response to Paragraph 236 of the Amended Complaint, Blouch admits that Invacare's stock price declined from \$23.81 per share on October 26, 2011, to close at \$22.80 per share on October 27, 2011. Blouch states that the October 27, 2011 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 236 is inconsistent with the October 27, 2011 Press Release, it is denied. Blouch denies the remaining allegations in Paragraph 236 of the Amended Complaint.
- 237. In response to Paragraph 237 of the Amended Complaint, Blouch admits that Invacare's stock price declined from \$20.58 per share on December 7, 2011, to close at \$14.70 per share on December 8, 2011. Blouch states that the December 8, 2011 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 237 is inconsistent with the December 8, 2011 Press Release, it is denied. Blouch denies the remaining allegations in Paragraph 237 of the Amended Complaint.
  - 238. Blouch denies the allegations in Paragraph 238 of the Amended Complaint.
- 239. In response to Paragraph 239 of the Amended Complaint, Blouch states that the December 8, 2011 WJB report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 239 is inconsistent with the December 8, 2011 WJB report, it is denied.
- 240. In response to Paragraph 240 of the Amended Complaint, Blouch states that the December 8, 2011 Great Lakes Review report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 240 is inconsistent with the December 8, 2011 Great Lakes Review report, it is denied.

- 241. In response to Paragraph 241 of the Amended Complaint, Blouch states that the December 8, 2011 CL King report speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 241 is inconsistent with the December 8, 2011 CL King report, it is denied.
  - 242. Blouch denies the allegations in Paragraph 242 of the Amended Complaint.
  - 243. Blouch denies the allegations in Paragraph 243 of the Amended Complaint.

# IX. ADDITIONAL SCIENTER ALLEGATIONS

- 244. Blouch denies the allegations in Paragraph 244 of the Amended Complaint.
- 245. Blouch denies the allegations in Paragraph 245 of the Amended Complaint.

# A. The FDA's Findings

246. In response to Paragraph 246 of the Amended Complaint, Blouch states that the FDA Complaint speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 246 is inconsistent with the FDA Complaint, it is denied. Blouch denies the remaining allegations in Paragraph 246 of the Amended Complaint.

# B. The Consent Decree

247. Blouch denies the allegations in Paragraph 247 of the Amended Complaint.

# C. The Duration Of The Scheme

248. Blouch denies the allegations in Paragraph 248 of the Amended Complaint.

# D. <u>Hiring And Abrupt Resignation Of Colleen Craven</u>

249. In response to Paragraph 249 of the Amended Complaint, Blouch admits that there was no position titled Chief Compliance Officer prior to 2011, admits that Invacare hired Colleen Craven to serve as its new Chief Compliance Officer, and admits that Invacare issued a press release on April 4, 2011 (the "April 4, 2011 Press Release"). Blouch states that the April 4,

2011 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 249 is inconsistent with the April 4, 2011 Press Release, it is denied.

- 250. In response to Paragraph 250 of the Amended Complaint, Blouch states that the April 4, 2011 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 250 is inconsistent with the April 4, 2011 Press Release, it is denied.
- 251. Blouch denies the allegations in Paragraph 251 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 252. In response to Paragraph 252 of the Amended Complaint, Blouch states that Invacare issued a press release on April 22, 2011 (the "April 22, 2011 Press Release"). Blouch states that the April 22, 2011 Press Release speaks for itself and, therefore, no response is required. To the extent any allegation set forth in Paragraph 252 is inconsistent with the April 22, 2011 Press Release, it is denied.
- 253. Blouch denies the allegations in Paragraph 253 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.

#### E. Defendants Capitalized On The Fraud

- 254. Blouch denies the allegations in Paragraph 254 of the Amended Complaint.
- 255. In response to Paragraph 255 of the Amended Complaint, Blouch admits that he did not purchase any Invacare common stock during the Class Period, denies all allegations relating to Mixon for want of knowledge or information sufficient to form a belief as to their truth, and denies the remaining allegations.

- 256. In response to Paragraph 256 of the Amended Complaint, Blouch denies all allegations relating to Mixon for want of knowledge or information sufficient to form a belief as to their truth and denies the remaining allegations.
  - 257. Blouch denies the allegations in Paragraph 257 of the Amended Complaint.
- 258. Blouch denies the allegations in Paragraph 258 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.

# F. Defendants' Culture Of Noncompliance And Contempt For The FDA

- 259. Blouch denies the allegations in Paragraph 259 of the Amended Complaint.
- 260. Blouch denies the allegations in Paragraph 260 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 261. Blouch denies the allegations in Paragraph 261 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 262. Blouch denies the allegations in Paragraph 262 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 263. Blouch denies the allegations in Paragraph 263 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 264. In response to Paragraph 264 of the Amended Complaint, Blouch admits that Invacare hired Doug Uelmen as Senior Vice President for Quality Assurance and Regulatory Affairs in December 2011, denies all allegations relating to CW4 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth, and denies the remaining allegations.
- 265. Blouch denies the allegations in Paragraph 265 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.

- 266. In response to Paragraph 266 of the Amended Complaint, Blouch denies all allegations relating to CW4 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth, and denies the remaining allegations.
- 267. Blouch denies the allegations in Paragraph 267 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 268. Blouch denies the allegations in Paragraph 268 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 269. Blouch denies the allegations in Paragraph 269 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 270. Blouch denies the allegations in Paragraph 270 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 271. Blouch denies the allegations in Paragraph 271 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 272. Blouch denies the allegations in Paragraph 272 of the Amended Complaint for want of knowledge or information sufficient to form a belief as to their truth.
- 273. In response to Paragraph 273 of the Amended Complaint, Blouch denies all allegations relating to CW5 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth, and denies the remaining allegations.
- 274. In response to Paragraph 274 of the Amended Complaint, Blouch admits that Invacare temporarily shut down production at the Taylor Street Facility on Friday, December 21, 2012 and denies all allegations relating to CW7 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth.

- 275. In response to Paragraph 275 of the Amended Complaint, Blouch denies all allegations relating to CW9 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth, and denies the remaining allegations.
- 276. In response to Paragraph 276 of the Amended Complaint, Blouch denies all allegations relating to CW9 and statements made by same for want of knowledge or information sufficient to form a belief as to their truth, and denies the remaining allegations.

# X. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR

277. The allegations in Paragraph 277 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.

# XI. CLASS ACTION ALLEGATIONS

- 278. The allegations in Paragraph 278 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.
- 279. The allegations in Paragraph 279 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.
- 280. The allegations in Paragraph 280 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.
- 281. The allegations in Paragraph 281 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.

282. The allegations in Paragraph 282 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further

response to the allegations is required, Blouch denies them.

283. The allegations in Paragraph 283 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.

XII. <u>LEAD PLAINTIFF RELIED UPON DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND OMISSIONS</u>

284. The allegations in Paragraph 284 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further

response to the allegations is required, Blouch denies them.

285. The allegations in Paragraph 285 of the Amended Complaint constitute legal

conclusions to which a response is neither warranted nor appropriate. To the extent that a further

response to the allegations is required, Blouch denies them.

286. The allegations in Paragraph 286 of the Amended Complaint constitute legal

conclusions to which a response is neither warranted nor appropriate. To the extent that a further

response to the allegations is required. Blouch denies them.

287. The allegations in Paragraph 287 of the Amended Complaint constitute legal

conclusions to which a response is neither warranted nor appropriate. To the extent that a further

response to the allegations is required, Blouch denies them.

XIII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

For Violation Of Section 10(b) Of The Exchange Act And Rule 10(b)(5)

Against Invacare, Blouch, And Mixon

- 288. In response to Paragraph 288 of the Amended Complaint, Blouch incorporates by reference Paragraphs 1 through 287 hereof as if fully rewritten herein.
- 289. The allegations in Paragraph 289 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.
  - 290. Blouch denies the allegations in Paragraph 290 of the Amended Complaint.
  - 291. Blouch denies the allegations in Paragraph 291 of the Amended Complaint.
  - 292. Blouch denies the allegations in Paragraph 292 of the Amended Complaint.
- 293. The allegations in Paragraph 293 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.
  - 294. Blouch denies the allegations in Paragraph 294 of the Amended Complaint.
  - 295. Blouch denies the allegations in Paragraph 295 of the Amended Complaint.
  - 296. Blouch denies the allegations in Paragraph 296 of the Amended Complaint.
  - 297. Blouch denies the allegations in Paragraph 297 of the Amended Complaint.
- 298. In response to Paragraph 298 of the Amended Complaint, Blouch denies that Invacare disclosed material adverse information, denies that Invacare made material misstatements, denies that Invacare common stock was purchased or otherwise acquired at artificially inflated prices, and denies the remaining allegations for want of knowledge or information sufficient to form a belief as to their truth.
  - 299. Blouch denies the allegations in Paragraph 299 of the Amended Complaint.
  - 300. Blouch denies the allegations in Paragraph 300 of the Amended Complaint.

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# SECOND CLAIM FOR RELIEF

# For Violation Of Section 20(a) Of The Exchange Act Against The Individual Defendants

- 301. In response to Paragraph 301 of the Amended Complaint, Blouch incorporates by reference Paragraphs 1 through 300 hereof as if fully rewritten herein.
- 302. The allegations in Paragraph 302 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.
- 303. The allegations in Paragraph 303 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.
- 304. The allegations in Paragraph 304 of the Amended Complaint constitute legal conclusions to which a response is neither warranted nor appropriate. To the extent that a further response to the allegations is required, Blouch denies them.
  - 305. Blouch denies the allegations in Paragraph 305 of the Amended Complaint.
  - 306. Blouch denies the allegations in Paragraph 306 of the Amended Complaint.

# AFFIRMATIVE DEFENSES

- 1. Lead Plaintiff fails to state a claim against Blouch upon which relief can be granted.
  - 2. Lead Plaintiff fails to plead fraud-based claims with the requisite particularity.

- 3. Some or all of Lead Plaintiff's claims against Blouch are barred by applicable statutes of limitation and/or statutes of repose.
- 4. Some or all of Lead Plaintiff's claims against Blouch are barred by the doctrines of unclean hands, laches, waiver, and/or estoppel.
- 5. Lead Plaintiff's claims against Blouch are barred by the doctrine of settlement and release.
- 6. Lead Plaintiff's claims against Blouch are barred by the defenses of *res judicata* and collateral estoppel.
- 7. Lead Plaintiff's claims against Blouch are barred, in whole or in part, because Lead Plaintiff failed to mitigate its damages.
- 8. Lead Plaintiff fails to allege the existence of any material misstatement or omission.
- 9. Lead Plaintiff fails sufficiently to allege that Blouch acted with the requisite scienter.
  - 10. Lead Plaintiff fails to allege sufficiently loss causation.
- 11. Lead Plaintiff's claims against Blouch are barred, in whole or in part, because the information Lead Plaintiff alleges Blouch failed to disclose was disclosed to the market through other reputable sources.

At the time that this Answer is being filed, Blouch's investigation into the facts is ongoing, and Blouch therefore reserves the right to amend this Answer and to assert any additional defenses as new facts are learned in the course of his investigation or through the discovery process.

# Respectfully submitted,

/s/ Fritz E. Berckmueller
MITCHELL G. BLAIR (0010892)
FRITZ E. BERCKMUELLER (0081530)
ERIC S. ZELL (0084318)
CALFEE, HALTER & GRISWOLD LLP
The Calfee Building
1405 East Sixth Street
Cleveland, OH 44114
Telephone: (216) 622-8200
Fax: (216) 241-0816
mblair@calfee.com
fberckmueller@calfee.com
ezell@calfee.com

Attorneys for Defendants, Invacare Corporation, Gerald B. Blouch, and A. Malachi Mixon, III

# **CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing was filed electronically on October 2, 2014.

Notice of this filing will be sent to all parties by operation of the Court's electronic filing system.

/s/ Fritz E. Berckmueller
One of the Attorneys for Defendants, Invacare
Corporation, Gerald B. Blouch, and A. Malachi
Mixon, III